## SETTLEMENT AGREEMENT BETWEEN STATE BOARD OF PHARMACY AND LIN-KRIS PHARMACY, INC. d/b/a CEDAR HILL DRUG

Come now Lin-Kris Pharmacy, Inc. d/b/a Cedar Hill Drug ("Respondent" or "Cedar Hill") and the Missouri Board of Pharmacy ("Board" or "Petitioner") and enter into this Settlement Agreement for the purpose of resolving the question of whether Respondent's permit to operate a pharmacy will be subject to discipline.

Pursuant to the terms of Section 536.060, RSMo, the parties hereto waive the right to a hearing by the Administrative Hearing Commission of the State of Missouri and, additionally, the right to a disciplinary hearing before the Board under Section 621.110, RSMo, and stipulate and agree that a final disposition of this matter may be effectuated as described below.

Respondent acknowledges that it understands the various rights and privileges afforded it by law, including the right to a hearing of the charges against it; the right to appear and be represented by legal counsel; the right to have all charges against it proved upon the record by competent and substantial evidence; the right to cross-examine any witnesses appearing at the hearing against it; the right to a decision upon the record by a fair and impartial administrative hearing commissioner concerning the charges pending against it and, subsequently, the right to a disciplinary hearing before the Board at which time it may present evidence in mitigation of discipline; and the right to recover attorney's fees incurred in defending this action against its permit. Being aware of these rights provided it by operation of law, Respondent knowingly and voluntarily waives each and every one of these rights and freely enters into this Settlement Agreement and agrees to abide by the terms of this document, as they pertain to it.

Respondent acknowledges that it has received a copy of the draft complaint to be filed with the Administrative Hearing Commission, the investigative report, and other documents relied upon by the Board in determining there was cause for discipline against Respondent's permit.

For the purpose of settling this dispute, Respondent stipulates that the factual allegations contained in this Settlement Agreement are true and stipulates with the Board that Respondent's permit to operate a pharmacy, numbered 2002005824, is subject to disciplinary action by the Board in accordance with the provisions of Chapter 621 and Chapter 338, RSMo.

#### JOINT STIPULATION OF FACTS

- 1. Petitioner, the Missouri Board of Pharmacy ("the Board"), is an agency of the State of Missouri created and established by Section 338.110, RSMo, for the purpose of administering and enforcing the provisions of Chapter 338, RSMo.
- 2. Respondent, Lin-Kris Pharmacy, Inc. d/b/a Cedar Hill Drug ("Cedar Hill" or "Respondent"), holds a pharmacy permit originally issued when they purchased the pharmacy on March 15, 2008, by the Board, Permit No. 2002005824, to operate a pharmacy at 6733 Mall Drive, Cedar Hill, Missouri. Cedar Hill's permit was issued on March 15, 2002 and continues to be current and active.
- 3. On or about May 17, 2005, the Board received a complaint concerning the actions of Cedar Hill Drug filling questionable prescriptions for controlled substances which were written by Dr. Harry M. Katz.
  - 4. In United States of America v. Harry Meyer Katz, United States District Court,

Eastern District of Missouri, Case No. S2-4:04CR324DJS, Dr. Katz was charged in a 192-count indictment with attempted or actual distribution of Schedule III and IV controlled substances outside the scope of medical practice and not for a legitimate medical purpose in violation of 21 U.S.C. §§ 846 and 841(a)(1).

- 5. Each count of Dr. Katz' indictment related to a single prescription written by Dr. Katz for various controlled substances including Xanax, Darvocet, Alprazolam, Vicodin and Valium.
- 6. A jury found Dr. Katz guilty on 176 counts of the indictment, and the District Court sentenced him to 16 months imprisonment, a \$75,000.00 fine and the forfeiture of \$5,640.00. The forfeiture of \$5,640.00 represented the amount of fees that Dr. Katz earned for the office visits in connection with the counts of conviction.
- 7. On May 23, 2005, Inspector Kidd issued a Drug Utilization Review request at Cedar Hill Drug requesting computer records for all prescriptions filled for Hydrocodone, Alprazolam and Carisoprodol.
  - 8. The timeframe for this request was May 11, 2000 to May 11, 2005.
- 9. While reviewing these prescriptions, it became apparent to Inspector Kidd that prescriptions for controlled substances were filled for patients that lived a long distance from the pharmacy.
- 10. Below is a table showing examples of patient's addresses, drive time and distance traveled to Cedar Hill Drug. (Mileage is based on MapQuest).

PATIENT ADDRESS	DRIVE TIME	DISTANCE TRAVELED
Rolla, Missouri	1 hour, 18 minutes	75.51 miles

St. Charles, Missouri	54 minutes	43.93 miles
St. John, Missouri	49 minutes	40.12 miles
Poplar Bluff, Missouri	2 hours, 34 minutes 1	135.67 miles
Vandalia, Illinois	1 hours, 46 minutes	103.67 miles
Belleville, Illinois	54 minutes	45.30 miles
Weldon Springs, Missouri	50 minutes	34.62 miles
Overland, Missouri	49 minutes	38.05 miles
Bloomsdale, Missouri	49 minutes	36.30 miles
St. Peters, Missouri	55 minutes	47.32
Winfield, Missouri	1 hr. 21 minutes	64.25
Boca Raton, Florida	18 hrs., 25 minutes	1,210.88
Potosi, Missouri	56 minutes	42.21
Bourbon, Missouri	49 minutes	43.35
Granite City, Illinois	58 minutes	44.88
St. Ann, Missouri	48 minutes	39.50
O'Fallon, Missouri	59 minutes	51.69
Wentzville, Missouri	1 hour, 1 minute	45.00
Collinsville, Illinois	59 minutes	50.06
Bloomsdale, Missouri	43 minutes	37.72
Rolla, Missouri	1 hour, 19 minutes	76.47
Centralia, Illinois	1 hour, 50 minutes	107.29
Overland, Missouri	49 minutes	38.62
Gerald, Missouri	1 hour, 3 minutes	46.83

- 11. Cedar Hill Drug filled prescriptions for controlled substances for patients that lived great distances from the pharmacy.
- 12. The distances traveled by the patients should have suggested to Cedar Hill Drug that the prescriptions were suspicious.
- 13. Cedar Hill Drug should have recognized the suspicious nature of the prescriptions which were written for patients who lived long distances from the pharmacy.
- 14. Upon further review of the requested records, Inspector Kidd found numerous prescriptions for controlled substances dispensed by Cedar Hill Drug that did not contain the name of the prescriber.

- 15. The records indicate the terms "DesPeres Hospital, St. Anthony's Hospital, Jefferson Memorial Hospital, St. Joseph Hospital, Barnes Hospital, DePaul Hospital, Forest Park Hospital and St. Louis University Hospital" were used instead of the name of the actual prescriber.
- 16. Cedar Hill Drug filled prescriptions for controlled substances that did not contain the name of the prescriber on the label.
- 17. Failing to list the name of the prescriber for controlled substance prescriptions is in violation of § 338.059, RSMo, which states in pertinent parts:
  - 1. It shall be the duty of a licensed pharmacist or a physician to affix or have affixed by someone under the pharmacist's or physician's supervision a label to each and every container provided to a consumer in which is placed any prescription drug upon which is typed or written the following information:

\* \* \*

- (5) The prescriber's name.
- 18. Failing to list the name of the prescriber for controlled substance prescriptions is in violation of Section 195.100.5, RSMo, which states:
  - 5. Whenever a pharmacist or practitioner sells or dispenses any controlled substance on a prescription issued by a physician, dentist, podiatrist or veterinarian, he shall affix to the container in which such drug is sold or dispensed, a label showing his own name and address of the pharmacy or practitioner for whom he is lawfully acting; the name of the patient or, if the patient is an animal, the name of the owner of the animal and the species of the animal; the name of the physician, dentist, podiatrist or veterinarian by whom the prescription was written; and such directions as may be stated on the prescription. No person shall alter, deface, or remove any label so affixed.
  - 19. Failing to list the name of the prescriber for controlled substance prescriptions is

in violation of 4 CSR 220-2.080(2) (n.k.a. 20 CSR 2220-2.080(2)) which states in pertinent parts:

(2) Any EDP system used by any pharmacy for record keeping shall comply with the requirements of section 338.100, RSMo, including the capability to store and retrieve the following information concerning the filling or refilling of any prescription:

\* \* \*

- 20. On or about August 30, 2005, Inspector Kidd interviewed Drug Enforcement Agency ("DEA") Agent William P. Stockmann regarding his involvement in the Dr. Katz trial and seizure of evidence from Cedar Hill Drug.
- 21. On or about September 16, 2005, Inspector Kidd received from Agent Stockmann two (2) Investigation Reports relating to Cedar Hill Drug and four (4) pages of charts labeled "Incidents per Zipcode".
- 22. On or about June 7, 2001, in conjunction with a State Search Warrant executed at the office of Harry M. Katz, M.D., the DEA served an Administrative Inspection Warrant on Cedar Hill Drug and conducted an inspection at the pharmacy.
- 23. The DEA investigators interviewed Richard R. Thornton, the pharmacist-incharge of Cedar Hill Drug, regarding the nature of the prescriptions being filled by Cedar Hill Drug for Dr. Katz.
- 24. Among other things, Mr. Thornton was questioned by the DEA inspectors about the patients of Dr. Katz.
- 25. Mr. Thornton stated to the inspectors that "Katz has a lot of questionable patients, a lot of people coming from South St. Louis City and St. Peters, Missouri."
  - 26. When asked if he had ever refused any of Dr. Katz' patients, Mr. Thornton stated

that he had refused only a few.

- 27. Mr. Thornton continued to fill prescriptions written by Dr. Katz even though he admitted to the DEA inspectors that Dr. Katz had a lot of "questionable patients".
- 28. During this inspection, all Schedule III through Schedule V controlled substance prescription records for the period June 3, 1999 through June 6, 2001 were seized from Cedar Hill Drug.
  - 29. On or about May 23, 2003, the DEA conducted an inspection of Cedar Hill Drug.
- 30. A computer printout of controlled substances prescriptions revealed that Cedar Hill Drug filled one hundred (100) controlled substance prescriptions prescribed by Dr. Katz on May 12, 2003.
- 31. Cedar Hill Drug filled a total of twenty (20) controlled substance prescriptions from May 13, 2003 to May 22, 2003.
- 32. Agent Stockmann advised Mr. Thornton that as of May 13, 2003, Dr. Katz had no authority to prescribe controlled substance prescriptions.
- 33. Cedar Hill pharmacy patients traveled from as far away as Warrenton, Troy, Cuba and Steelville, Missouri; and from Granite City and O'Fallon, Illinois.
- 34. Cedar Hill pharmacy patients traveled 100+ miles and from as far away as Fulton, Jefferson City, Bloomfield, Chaffee, Cape Girardeau and Salem, Missouri; and from Greenville and Salem, Illinois.
- 35. Cedar Hill pharmacy patients traveled 150+ miles and from as far away as Osage Beach, Carrollton, Forsyth and Ozark, Missouri; from Mt. Vernon, Illinois; from Clinton, Kentucky; and from Clarksville, Tennessee.

- 36. Cedar Hill pharmacy patients traveled 200+ miles and from as far away as Gainesville, Missouri; from Tulsa, Oklahoma, from Holton, Kansas; from Muncie, Indiana; from Dickson, Tennessee and from Springfield, Illinois.
- 37. Pharmacists have a responsibility for the proper dispensing of controlled substances.
- 38. Cedar Hill knowingly filled suspicious prescriptions in violation of 21 CFR 1306.04(a) which states as follows:
  - (a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances
- 39. Cedar Hill Drug should have recognized the suspicious nature of the prescriptions which were written for patients who lived long distances from the pharmacy.
- 40. Federal and state laws regulating controlled substances exist because of a recognition that these substances are dangerous to the public if not properly prescribed and dispensed.
- 41. Controlled substances are dangerous when not taken for a legitimate medical purpose.
  - 42. Controlled substances are susceptible to misuse and abuse.

- 43. Cedar Hill Drug violated and assisted or enabled another person to violate Missouri rules and regulations governing the practice of pharmacy by continuing to fill suspicious prescriptions for controlled substances.
- 44. The employees and customers of Cedar Hill Drug had a relationship of professional trust and confidence in Cedar Hill Drug in that employees and customers rely on Cedar Hill Drug to make reasonable efforts to ensure compliance with all relevant pharmacy and drug laws and standards of practice.
- 45. Cedar Hill Drug's conduct alleged herein constitutes a violation of the professional trust and confidence placed in Cedar Hill Drug by its employees and customers.
- 46. Cedar Hill Drug should have known that violations of pharmacy laws or rules had occurred.
- 47. Cedar Hill Drug did not assure that all state and federal laws concerning drug distribution and control were complied with so that no violations occurred.
- 48. Respondent's conduct alleged herein constitutes a violation of the drug laws and regulations of this state and of the federal government.

### JOINT CONCLUSIONS OF LAW

- 49. Cause exists for Petitioner to take disciplinary action against Cedar Hill's permit under 20 CSR 2220-2.010(1)(O) which states:
  - (O) When a pharmacy permit holder knows or should have known, within the usual and customary standards of conduct governing the operation of a pharmacy as defined in Chapter 338, RSMo, that an employee, licensed or unlicensed, has violated the pharmacy laws or rules, the permit holder shall be subject to discipline under Chapter 338, RSMo.

- 51. Cause exists for Petitioner to take disciplinary action against Cedar Hill's permit under Section 338.055, RSMo, which states in relevant parts:
  - 2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his or her certificate of registration or authority, permit or license for any one or any combination of the following causes:

\* \* \*

- (5) Incompetence, misconduct, gross negligence, fraud, misrepresentation or dishonesty in the performance of the functions or duties of any profession licensed or regulated by this chapter;
- (6) Violation of, or assisting or enabling any person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter.

\* \* \*

(13) Violation of any professional trust or confidence;

\* \* \*

- (15) Violation of the drug laws or rules and regulations of this state, any other state or the federal government.
- 52. Cause exists for Petitioner to take disciplinary action against Cedar Hill's permit under Section 338.285, RSMo, which states:

The board is hereby authorized and empowered, when examination or inspection of a pharmacy shall disclose to the board

that the pharmacy is not being operated or conducted according to such legal rules and regulations and the laws of Missouri with respect thereto, to cause a complaint to be filed before the administrative hearing commission pursuant to chapter 621, RSMo, charging the holder of a permit to operate a pharmacy with conduct constituting grounds for discipline in accordance with section 338.055.

#### JOINT AGREED DISCIPLINARY ORDER

Based upon the foregoing, the parties mutually agree and stipulate that the following shall constitute the disciplinary order entered by the Board in this matter under the authority of Section 621.045.3, RSMo:

- 1. Respondent's permit to operate a pharmacy shall be placed on PROBATION for a period of three (3) years. The period of probation shall constitute the disciplinary period. The terms of discipline shall be as follows:
  - A. Respondent shall keep the Board apprised of licensed pharmacists employed by Respondent and the individuals' current home and work addresses and telephone numbers.
  - B. Respondent shall pay all required fees for permitting to the Board and shall renew its permit prior to October 31 for each permitting year.
  - C. Respondent shall comply with all provisions of Chapter 338 and 195; all applicable federal and state drug laws, rules and regulations; and all federal and state criminal laws. "State" here includes the State of Missouri and all other states and territories of the United States.
    - D. Respondent shall not serve as an intern training facility for interns.

- E. If, after disciplinary sanctions have been imposed, Respondent fails to keep its Missouri pharmacy permit current, the period of unlicensed status shall not be deemed or taken as any part of the time of discipline so imposed.
- F. The parties to this Agreement understand that the Board of Pharmacy will maintain this Agreement as an open record of the Board as provided in Chapters 338, 610, and 620, RSMo.
- G. Respondent shall conduct an Initial Inventory at this pharmacy on all scheduled controlled substances, including Carisoprodol. The Initial Inventory shall be immediately available to a member of the Board or the Board of Pharmacy staff.
- H. Respondent shall report to the Board, on a preprinted form supplied by the Board office, once every six (6) months (due by each January 1 and July 1), beginning with whichever date occurs first and after this Order/Agreement becomes effective, stating truthfully whether or not it has complied with all terms and conditions of this disciplinary order.
- I. Respondent shall select an independent consultant for the purpose of reviewing and insuring all compliance measures are carried out in accordance with all applicable laws and regulations. Respondent shall submit documentation and credentials of his chosen consultant to the Board office for approval prior to the beginning date of probation. Said consultant shall submit a written plan to the Board office outlining what procedures or changes in operation will be implemented and on what time table is proposed for completion. The consultant shall then provide ongoing reports to the Board office attesting to the pharmacy's compliance or noting deficiencies for each visit made.

The visits and initial report shall be provided within thirty (30) days of the beginning of probation. Visits to the pharmacy to assess compliance will be completed at a minimum of a six (6) month cycle and reports to the Board office will be provided once every six (6) months throughout the disciplinary period. The consultant shall be hired at Respondent's expense.

- J. Visits and reports of the consultant can be reduced to an annual visit after two (2) years pending performance and compliance with this Agreement and with the state and federal drug laws.
- 2. Upon the expiration of said discipline, Respondent's permit to operate a pharmacy in Missouri shall be fully restored if all other requirements of law have been satisfied; provided, however, that in the event the Board determines that the Respondent has violated any term or condition of this Settlement Agreement, the Board may, in its discretion, after an evidentiary hearing, vacate and set aside the discipline imposed herein and may suspend, revoke, or otherwise lawfully discipline the Respondent.
- 3. No order shall be entered by the Board pursuant to the preceding paragraph of this Settlement Agreement without notice and an opportunity for hearing before the Board in accordance with the provisions of Chapter 536, RSMo.
- 4. If the Board determines that Respondent has violated a term or condition of this Settlement Agreement, which violation would also be actionable in a proceeding before the Administrative Hearing Commission or the circuit court, the Board may elect to pursue any lawful remedies or procedures afforded it and is not bound by this Settlement Agreement in its determination of appropriate legal actions concerning that violation. If any alleged violation of

this Settlement Agreement occurred during the disciplinary period, the Board may choose to conduct a hearing before it either during the disciplinary period, or as soon thereafter as a hearing can be held to determine whether a violation occurred and, if so, it may impose further discipline. The Board retains jurisdiction to hold a hearing to determine if a violation of this Settlement Agreement has occurred.

- 5. The terms of this Settlement Agreement are contractual, legally enforceable, binding, and not merely recitals. Except as otherwise contained herein, neither this Settlement Agreement nor any of its provisions may be changed, waived, discharged, or terminated, except by an instrument in writing signed by the party against whom the enforcement of the change, waiver, discharge, or termination is sought.
- 6. Respondent hereby waives and releases the Board, its members and any of its employees, agents, or attorneys, including any former board members, employees, agents, and attorneys, of, or from, any liability, claim, actions, causes of action, fees, costs and expenses, and compensation, including, but not limited to, any claims for attorney's fees and expenses, including any claims pursuant to Section 536.087, RSMo, or any claim arising under 42 U.S.C. Section 1983, which may be based upon, arise out of, or relate to any of the matters raised in this litigation, or from the negotiation or execution of this Settlement Agreement. The parties acknowledge that this paragraph is severable from the remaining portions of this Settlement Agreement in that it survives in perpetuity even in the event that any court of law deems this Settlement Agreement or any portion thereof void or unenforceable.

RESPONDENT, AS EVIDENCED BY THE INITIALS ON THE APPROPRIATE LINE,

	REQ	UESTS

# DOES NOT REQUEST

THE ADMINISTRATIVE HEARING COMMISSION TO DETERMINE IF THE FACTS SET FORTH HEREIN ARE GROUNDS FOR DISCIPLINING RESPONDENT=S PERMIT TO OPERATE A PHARMACY.

If Respondent has requested review, Respondent and Board jointly request that the Administrative Hearing Commission determine whether the facts set forth herein are grounds for disciplining Respondent's permit and issue findings of fact and conclusions of law stating that the facts agreed to by the parties are grounds for disciplining Respondent's permit. Effective the date the Administrative Hearing Commission determines that the Settlement Agreement sets forth cause for disciplining Respondent's permit, the agreed upon discipline set forth herein shall go into effect.

If Respondent has not requested review by the Administrative Hearing Commission, the Settlement agreement goes into effect 15 days after the document is signed by the Board's Executive Director or a representative of the Board.

RESPONDENT

LIN-KRIS PHARMACY, INC. d/b/a CEDAR HILL DRUG

By:

Roy II. Eberhart, II

President

Date: 10-15-08

By:

MISSOURI BOARD OF

Date:

By:

**PETITIONER** 

**PHARMACY** 

ARMSTRONG TEASDALE LLP

By:

Kim S. Burton 3405 West Truman Blvd. Jefferson City, MO 65109-5713

Telephone: 573/636-8394

Fax: 573/636-8457

Attorneys for Respondent

NEWMAN, COMLEY & RUTH

P.C.

Lanette R. Gooch #47860 601 Monroe, Suite 301

P.O. Box 537

Jefferson City, MO 65102-0537

Telephone: 573/634-2266

Fax: 573/636-3306

Attorneys for Petitioner

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